

Patent Claims

We Claim:

1. A method for treating or preventing a condition selected from
5 headaches and migraine, said method comprising the simultaneous or sequential administration of: (1) a therapeutically effective amount of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine and (2)
10 a therapeutically effective amount of sumatriptan, or one of the physiologically acceptable salts thereof, to a person in need of such treatment.
2. A method according to claim 1, wherein the condition is a cluster headache.
- 15 3. A method according to claim 1, wherein the sequential administration comprises first administering a therapeutically effective amount of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine and subsequently administering a therapeutically effective amount of sumatriptan,
20 or one of the physiologically acceptable salts thereof.
4. A method according to claim 1, wherein the sequential administration comprises first administering a therapeutically effective amount of sumatriptan, or one of the physiologically acceptable salts thereof, and
25 subsequently administering a therapeutically effective amount of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine.
5. A method according to claim 1, wherein the hydrochloride of
30 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]- carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine is administered by intravenous or subcutaneous route in a dosage of 0.0001 to 3 mg/kg of body weight or by oral, nasal, rectal or inhalative route in a dosage of 0.1 to 10 mg/kg of body weight, once, twice or three times a day, and sumatriptan or a

physiologically acceptable salt thereof is administered:

by oral route in a dosage of 0.14 to 1.5 mg/kg of body weight once, twice or three times a day, or

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by intravenous or subcutaneous route in a dosage of 0.009 to 0.1 mg/kg of body weight once or twice a day, or

10 by rectal route in a dosage of 0.04 to 0.36 mg/kg of body weight once or twice a day, or

by inhalation in a dosage of 0.057 to 0.57 mg/kg of body weight once or twice a day, or

15 by nasal route in a dosage of 0.036 to 0.29 mg/kg of body weight once or twice a day.

6. A pharmaceutical composition comprising a therapeutically effective amount of a combination of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine and sumatriptan or one of the physiologically acceptable salts thereof.

20 7. A pharmaceutical composition according to claim 6, comprising a single dosage unit of 0.1 to 10 mg of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-(4-pyridinyl)-piperazine and a single dosage unit of 1 to 100 mg sumatriptan.

30 8. A kit comprising:

(a) a first enclosure containing a pharmaceutical composition comprising a therapeutically effective amount of the hydrochloride of 1-[N²-[3,5-dibromo-N-[[4-(3,4-dihydro-2(1H)-oxoquinazolin-3-yl)-1-piperidinyl]-carbonyl]-D-tyrosyl]-L-lysyl]-4-

(4-pyridinyl)-piperazine and one or more pharmaceutically acceptable diluents and/or carriers; and

- 5 (b) a second enclosure containing a pharmaceutical composition comprising sumatriptan, or a physiologically acceptable salt thereof, and one or more pharmaceutically acceptable diluents and/or carriers.